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ATTORNEYS FOR PLAINTIFFS

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

CODY LABORATORIES, INC., a Wyoming corporation, and LANNETT CO., INC., a Delaware corporation, Plaintiffs, v. THE HONORABLE KATHLEEN SEBELIUS, SECRETARY, U.S. Department of Health and Human Services, and DR. MARGARET A. HAMBURG, COMMISSIONER, U.S. Food and Drug Administration, Defendants.	)	Civil Action No. 10-CV-147J

COMPLAINT FOR
DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Plaintiffs Cody Laboratories, Inc. ("Cody") and its parent corporation Lannett Co., Inc. ("Lannett") (collectively "Cody/Lannett"), by and through their undersigned counsel, file the following Complaint seeking a declaratory judgment, temporary and permanent injunctive relief, and such other equitable relief as the Court may deem necessary and appropriate. In support of their claims, Cody/Lannett state the following:

PRELIMINARY STATEMENT

1. Cody/Lannett respectfully bring this action for a declaratory judgment and injunctive relief because the United States Food and Drug Administration ("FDA") is acting in an arbitrary and capricious manner, abusing its discretion, and acting contrary to law in seeking to force Cody/Lannett out of the market for the generic drug product Morphine Sulfate Solution Immediate Release Concentrated 20 mg/mL (the "Product"). Cody/Lannett seek a declaration that the position of the FDA, as stated in its warning letters dated March 30, 2009 and follow-up letters dated April 9, 2009, March 1, 2010, March 13, 2010, and June 22, 2010, is unlawful and that the FDA is not empowered to take action against Cody/Lannett to prevent Cody/Lannett from manufacturing, marketing, and selling the Product after July 24, 2010 solely because Cody/Lannett do not have an approved New Drug Application ("NDA"). The FDA's action violates the Administrative Procedures Act, 5 U.S.C. § 706(2)(A) ("APA"), and the Food Drug and Cosmetic Act, 21 U.S.C. §301, et seq. ("FDCA"). It is having a dire effect on Cody/Lannett's ability to manufacture, market, and sell medically necessary, lower cost, generic drugs for the benefit of the public health. Cody/Lannett have suffered and will continue to suffer

irreparable injury by the FDA's threatened enforcement actions, as such actions have caused a steep decline in the manufacture and sale of the Product by Cody/Lannett.

PARTIES

2. Plaintiff, Cody, is a Wyoming corporation with its principal and only place of business located at 601 Yellowstone Avenue, Cody, Wyoming 82414. It manufactures and sells in interstate commerce generic drugs, including the Product.

3. Plaintiff, Lannett, is a Delaware corporation with its principal place of business at 9000 State Road, Philadelphia, PA 19136. It markets and sells generic drugs manufactured by Cody in interstate commerce, including the Product.

4. Defendant, Kathleen Sebelius, named in her official capacity, is the Secretary of the United States Department of Health and Human Services ("Department"). The FDA is a component of the Department, and the Department is responsible for the administration of the FDA and its authorizing statute, the FDCA. The Secretary's office is in Washington, D.C.

5. Defendant, Dr. Margaret A. Hamburg, named in her official capacity, is the Commissioner of Food and Drugs who has been delegated the responsibility to administer the FDCA. 2 FDA Staff Manual Guides § 1410.10 (2005), available at http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm; 21 USCA § 393(d). The Commissioner's office is in Silver Spring, M.D.

JURISDICTION, VENUE, AND JUSTICIABILITY

6. The Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §1331, 5 U.S.C. § 706, and 28 U.S.C. § 2201.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1) because Cody's principal and only place of business is in this District and because the Product is manufactured and sold in this District.

8. This case is ripe for judicial review because the FDA has taken final agency action for which no other adequate remedy in court exists, Cody/Lannett have exhausted their administrative remedies, and they have suffered injury and will suffer irreparable injury unless this Court grants the relief requested. See generally 5 U.S.C. § 704; Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50-51 (1938); Abbott Lab. v. Gardner, 387 U.S. 136, 148-49 (1967).

BACKGROUND FACTS

I. Cody/Lannett

9. Cody is a wholly-owned subsidiary of Lannett. It is a manufacturer of generic drugs in Cody, Wyoming. It has been in operation since 2000. Cody manufactures the Product from its plant in Cody, Wyoming.

10. Lannett is the corporate parent of Cody. It is a company specializing in the manufacturing, marketing, and sales of generic drugs. It has been in operation since 1942. Lannett markets and sells the Product.

11. Cody has been a wholly-owned subsidiary of Lannett since 2007.

12. Cody/Lannett have extensive expertise in the development, manufacture, sale, marketing, and distribution of pharmaceutical products under their generic chemical names for human use.

13. Cody/Lannett have knowledge, skill, and experience in managing the development and production of pharmaceutical drug products from concept through approval by the FDA for marketing. In the course of its existence, Lannett has developed and brought to market over 100 generic drug products with Abbreviated New Drug Applications ("ANDAs") as well as a small number of drugs that have been in use since before the enactment of the FDCA in 1938. These pre-1938 drugs are, therefore, considered "unapproved drugs" under the FDCA.

14. Cody/Lannett are small companies. However, they compete with nearly every manufacturer and distributor of generic drugs, many of whom are owned by large, multi-national corporations.

15. Cody/Lannett expend considerable effort, time, and expense identifying opportunities for generic drug development and manufacturing, formulating strategies for the development, manufacture, marketing, and sale of generic drugs (from concept through FDA approval to commercialization). In that process Cody/Lannett develop and maintain relationships with vendors, suppliers, distributors, customers, and other pharmaceutical manufacturers.

II. Morphine Sulfate Immediate Release Concentrated Oral Solution 20 mg/mL

16. Morphine Sulfate is a pain medication that has been in use in the United States for more than 150 years.

17. Morphine Sulfate Immediate Release Concentrated Oral Solution 20 mg/mL is the generic chemical name of a controlled prescription drug that treats pain.

18. Morphine Sulfate is indicated "for the relief of moderate to severe acute and chronic pain" or "for the relief of severe acute and severe chronic pain." There are a number of dosage strengths and forms (solid oral tablets, oral solution, and injected), and the dosing varies based on the condition being treated and the needs of the patient.

19. The Active Pharmaceutical Ingredient (or Active Drug Substance) in Morphine Sulfate is Morphine, an opiate controlled as a Schedule II drug under the Comprehensive Drug Abuse Prevention and Control Act.

20. On or before 1938, Morphine Sulfate was legally marketed and subject to the provisions of the Food and Drugs Act of 1906.

21. Cody/Lannett's primary competitor in the market for the Product is Roxane Laboratories, Inc. ("Roxane"), a subsidiary of Boehringer Ingleheim located in Columbus, Ohio.

III. Cody/Lannett's Morphine Sulfate Solution

22. Cody/Lannett have been manufacturing, marketing, and selling the Product, in the United States for more than five years. Rights to the product were purchased from Liquipharm, Inc., which had marketed the product since 1984.

23. The Product is a concentrated liquid intended to be delivered orally to patients with chronic or acute pain. The concentrated nature of the Product makes it ideal for patients who cannot tolerate intravenous morphine and those who are unable to swallow more heavily diluted forms of the drug.

24. The most common use of the Product is in relieving the acute and chronic pain of terminally ill patients in hospitals, hospices, and palliative care communities.

25. When Cody began to manufacture the Product, information about the Product and its manufacturer were submitted to the FDA's Drug Registrations and Listing System.

IV. History/Structure of the FDCA and Its Application to Morphine Sulfate

26. In 1906, Congress enacted the Food and Drugs Act, which gave the government certain oversight authority over various products, including drugs. 34 Stat. 768 (1906).

27. In 1938, Congress passed the FDCA, which gave the FDA authority to oversee the safety of food, drugs, and cosmetics. It required premarket review of new drugs for safety. 21 U.S.C. § 301 et seq. (1938).

28. In 1962, Congress amended the FDCA to include authority over the effectiveness of drugs. The 1962 Amendments expanded FDA's premarket review of new drugs to include efficacy. 21 U.S.C. § 301 et seq. (1962).

29. Under the FDCA, Congress expressly determined that the provisions of the FDCA should only be applied to "new drugs" rather than the class of drugs that were already in use before 1938.

30. The grandfather provision in the 1938 Act states that a drug shall not be deemed a "new drug" that requires approval by the FDA "if at any time prior to the enactment of this Act [June 25, 1938] it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the condition of its use." 21 U.S.C. § 321(p)(1) (1938).

31. Morphine Sulfate solution was subject to the Food and Drugs Act of 1906, as amended.

32. Morphine Sulfate had labeling that contains the same representations concerning the conditions of its use when it was subject to the Food and Drug Act of 1906 (as concentrated oral Morphine Sulfate solution, including the Product, does now).

33. The Product is not a "new drug" within the meaning of the FDCA, and, therefore, an NDA is not required to be filed for the Product under the FDCA.

34. Drugs which fall within the grandfather provision of the FDCA are frequently referred to as "unapproved drugs" simply because the drugs have been commonly used for so long that manufactures and sellers of these "unapproved drugs" are not required to file an NDA with the FDA in order to manufacture, market, and sell the drugs in the United States.

35. Among the thousands of "unapproved drugs" that are manufactured, sold, and prescribed every day in the United States there are hundreds of commonly recognized and safely used medications.

36. This wide class of older "unapproved drugs" does not exist wholly outside of the significant regulatory apparatus of the FDA because such products are still categorized as "drugs" under the FDCA.

37. "Unapproved drugs," including the Product, are manufactured in facilities subject to FDA inspection every two years, or more often based on cause, for full compliance with current good manufacturing practice regulations.

38. Manufacturers and others are required to report adverse events related to "unapproved drugs" to the FDA.

39. The FDA can immediately pull "unapproved drugs" from the market if they are shown to cause harm to the public.

40. "Unapproved drugs" are commonly studied, recommended, and prescribed by the medical community.

FACTS

I. FDA 2006 Guidance

41. In 2006, the FDA, without making formal findings or using traditional notice and comment rulemaking, issued a compliance policy guidance related to "unapproved drugs." The FDA stated its view that the grandfathering provisions of the FDCA were no longer applicable to all or virtually all of the thousands of "unapproved drugs" then being sold in the United States. See Exhibit A.

42. The FDA determined unilaterally in this non-binding guidance, with virtually no administrative record, that any of these older drugs not then approved by the FDA in an NDA or ANDA, were subject to enforcement action as unapproved "new drugs" without regard to any evidence with respect to the length of time a particular drug had been in use or the indications for or labeling of such drugs prior to 1938.

43. In issuing this 2006 guidance, the FDA made no individualized determinations as to any particular drug, nor did it raise any safety concerns with respect to any individual drug or develop any administrative record regarding any individual drug.

44. In the 2006 guidance, the FDA did not order the removal of all "unapproved drugs" from the market. The FDA itself recognized that many such drugs were medically necessary, and the public interest demanded that such drugs remain available for medical use.

45. In the 2006 guidance, FDA set forth criteria under which it would exercise its discretion in initiating enforcement proceedings to remove particular, (but unnamed) "unapproved drugs" from the market.

46. As a grandfathered drug, the Product is not subject to the "new drug" requirements of the FDCA. It does not require FDA approval before it can be manufactured, marketed, and sold in the United States.

47. The FDA guidance, which operated effectively to render the grandfather provisions of the FDCA inoperative, is contrary to the express terms of the statutory grandfather provisions of the FDCA, through which Congress expressed an unequivocal intent that the FDCA apply only prospectively to "new drugs" and not retroactively to drugs on the market at the time of its passage.

II. The FDA's Warning Letters and Cody/Lannett's Good Faith, Diligence and Cooperation with the FDA

48. On or about March 30, 2009, the FDA sent warning letters to Cody/Lannett (collectively "March 2009 warning letters") as well as other drug manufacturers, stating in part that Morphine Sulfate products were "new drugs [under the FDCA] and not grandfathered and that manufacturing and marketing of these products without an approved application constituted a violation of the Act." See Exhibits B and C.

49. Prior to asserting that the FDCA's NDA requirement applied to these drugs sold prior to 1938 and continuously until the FDA's action, the FDA created no administrative record to justify its determination that Morphine Sulfate products were suddenly "new drugs."

50. In the March 30, 2009 warning letters, the FDA threatened Cody/Lannett with enforcement action.

51. The FDA's March 30, 2009 warning letters to Lannett and to Cody stated as follows:

> "You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other Federal agencies may take this Warning Letter into account when considering the award of contracts."

52. In the March 30, 2009 warning letters, the FDA stated unequivocally that enforcement actions would be taken if manufacturing continued for more than 60 days after the warning letters or if the drugs were still being shipped in interstate commerce more than 90 days after the date of the warning letters.

53. Upon receipt of their March 30, 2009 warning letters, Cody/Lannett promptly requested an extension of time to respond to the letters, which was granted, and Cody/Lannett sought a meeting with FDA. They also informed the Office of Compliance that the concentrated solution was a niche product important in palliative care, and the warning letters would likely create a drug shortage. The FDA informed Cody/Lannett that the shortage issue had been thoroughly researched by the Drug Shortage Office and that no shortage would occur.

54. On April 8, 2009, the FDA Drug Shortage Office contacted Cody/Lannett concerning a shortage of the 20 mg/mL oral Morphine Sulfate solution needed by hospice palliative care patients. At the FDA's request, Cody/Lannett increased production to respond to the shortage.

55. On April 9, 2009, the FDA announced that it was revising its position and would permit Morphine Sulfate oral solution to remain on the market in light of the public health need. It issued follow-up letters to the producers of concentrated Morphine Sulfate solution, including Cody/Lannett, permitting the drug to stay on the market for 180 days after the FDA first approved an NDA for the concentrated solution. See Exhibits D and E.

56. Shortly after FDA's issuance of the March 30, 2009 warning letters, Cody/Lannett's counsel contacted the FDA Center for Drug Evaluation and Research ("CDER") Office of Compliance and requested a face-to-face meeting to discuss the situation and path to approval.

57. On April 15, 2010, representatives of FDA and Cody/Lannett met. FDA denied that the Product, or any product currently marketed in the United States, was grandfathered under the FDCA and requested submission of an NDA.

58. On or about April 20, 2009, Cody/Lannett requested a meeting with the review division as expeditiously as possible to discuss the clinical requirements of such a filing, and followed the request up with a letter fulfilling the regulatory requirements for a pre-Investigational New Drug ("IND") review request and providing certain data to FDA.

59. Despite the priority nature of the matter, on April 29, 2009, the review division responded that it was "setting up a teleconference with Lannett in June."

60. In the May 1, 2009 responses to the March 30, 2009 warning letters and April 9, 2009 follow-up letters, Cody/Lannett indicated that, although they believed that the Product could be lawfully manufactured, marketed, and sold without FDA approval as a grandfathered pre-1938 drug, Cody/Lannett expected to be able to submit an NDA for the product by the end of 2009. See Exhibit F and G.

61. On May 29, 2009, the FDA issued letters to Cody/Lannett disagreeing that the Product was grandfathered and indicating its position that any company making such a claim was required by FDA regulation to provide certain information to the FDA to establish certain facts concerning whether the Product had "the same formulations, strengths, dosage forms, routes of administration, indications, intended patient populations, and other conditions of use as the pre-1938 or 1962 products." In other words, the FDA set forth its position that a company must engage in the NDA application process to prove that it is not required by the FDCA to file an NDA. See Exhibits H and I.

62. On July 1, 2009, the meeting with the FDA that Cody/Lannett had requested on April 20, 2009 took place.

63. On August 19, 2009, Cody/Lannett's counsel requested assistance from the FDA to clarify to the DEA Cody/Lannett's need for additional quota to produce the Product in response to the FDA's request for assistance in managing the product shortage. Cody had previously been denied additional quota by the DEA, apparently due to the FDA's March 30,

2009 warning letters and subsequent FDA discussions with DEA indicating the drugs were illegal "unapproved drugs."

64. On August 25, 2009, the FDA responded by denying that it had ever requested that Cody/Lannett increase production of the Product, claiming (among other things) that Cody/Lannett had refused to provide it certain data and that other data indicated that Cody/Lannett had not shown the capability to expand their production. In fact, Cody/Lannett had more than quadrupled their production of the Product, had hired more employees, and had otherwise demonstrated the ability to alleviate the shortage of concentrated oral Morphine Sulfate solution by supplying nearly 50% of the existing market.

65. Also on August 25, 2009, unbeknownst to Cody/Lannett, Roxane filed a Supplemental NDA for approval of its Morphine Sulfate oral solution 20 mg/mL. Roxane made additional submissions on October 30, November 5 and 18, December 1, 9, 17, and 18, 2009 and January 12, 2010.

66. On January 25, 2010, FDCA approved Roxane's supplemental NDA for morphine sulfate oral solution in larger bottles; 100 mg/5 mL, in an expedited priority review.

67. On January 26, 2010, the FDA issued a press release announcing the approval of Roxane's morphine sulfate oral solution NDA and held a conference call with the media. The FDA announced that it had worked with Roxane to ensure adequate supplies of the drug and that the agency would "also be working with patient organizations and prescribers so that they are aware that an approved product is available, and can notify FDA if there are any problems with

availability." See Exhibit J. The release linked to the March 30, 2009 warning letters, but not the April 9, 2009 extension of the enforcement date.

68. A news report about the FDA's announcement highlighted how unusual the FDA's actions were, including reporting that the "FDA is taking an unusually active role in helping a manufacturer ensure the supply of one of its own products" and that "[t]hrough its Drug Shortage Program, the FDA will closely monitor the inventory and sales data to availability of the product and provide a 1-800 number to pharmacies and health care providers, enabling them to order it directly from the manufacturer in the event there is any difficulty obtaining the product through the normal channels from their wholesalers or distributors." See Exhibit K. The report also stated that "FDA expects all the demand to shift its [Roxane's] way." See Exhibit K.

69. On January 27, 2010 and despite the previously announced grace period for other producers of concentrated oral Morphine Sulfate solution, which would not expire for 6 additional months, and as Cody/Lannett completed the clinical studies required to file their NDA, the FDA updated its drug shortage website on oral Morphine Sulfate solution. It only made reference to Roxane. It did not mention that, even under its previously announced deadline, other manufacturers could continue to make and distribute their products until July 24, 2010.

70. The listing on the FDA website has not been updated. The current update states "Roxane Laboratories has recently received FDA approval for Morphine Sulfate Oral solution 100 mg/5 ml (20 mg/mL). This is the only FDA approved morphine sulfate oral solution

available at this concentration. The firm has sufficient supply to meet the entire market demand and no shortage is anticipated." See Exhibit L.

71. As a result of the actions of the FDA, including negative statements made to the press, Cody's sales to Lannett and Lannett's sales of the drugs on the market were adversely affected.

72. On February 3, 2010 Cody/Lannett sought the FDA's assistance in correcting the misunderstandings in the marketplace that were arising as a result of the press coverage of the Roxane approval. Cody/Lannett received multiple reports from their sales force that representatives of Roxane approached Cody/Lannett customers to solicit business by informing them that Cody/Lannett's Products were "unapproved" and would not be available after July 24, 2010.

73. In response to Cody/Lannett's request for assistance, on February 4, 2010, Dr. Throckmorton, Deputy Director of CDER committed to Cody/Lannett that someone from CDER's Office of Compliance would respond to Cody/Lannett. On February 23, 2010 Cody/Lannett followed up with Dr. Throckmorton, noting that no one from CDER Compliance had contacted Cody/Lannett as had been promised.

74. On February 26, 2010, the earliest practicable date that Cody/Lannett could file an NDA given the expensive, time consuming, and voluminous requests for new clinical data by the FDA Review Division (including 180 day stability data), Lannett submitted its NDA for the Product to the FDA. Thus, Lannett filed its NDA approximately five months before the grace

period expired—leaving the FDA with enough time to approve its application if the FDA acted on an expedited basis, given the enforcement deadline, as it had for Roxane's application.

75. On March 1, 2010, the FDA issued letters to the manufacturers and distributors of the "unapproved" versions of 20 mg/mL oral Morphine Sulfate solution. See Exhibit M and N. In the letters to Cody/Lannett, the FDA informed them that, as a result of the approval of the Roxane NDA, the FDA would exercise its enforcement discretion with respect to the shipment/distribution of the Product only until July 24, 2010, and that distribution thereafter "may result in legal action without further notice, including, without limitation, seizure and injunction." See Exhibit M and N. The letter purported to remind Lannett that "all firms that market unapproved drugs to the American public are expected to submit the required applications to obtain approval for those products. . . . We encourage firms marketing any unapproved drugs to obtain FDA's approval for their products." See Exhibit M and N.

76. Despite previous communication authorizing the FDA to publicize the status of Lannett's NDA, the letter did not acknowledge that Lannett had submitted its NDA to CDER on February 26, 2010, and, thus, that Lannett had already taken the steps that the letter outlined.

77. FDA posted the March 1, 2010 letter on its website and sent a copy to DEA.

78. On March 4, 2010, the CEO of Lannett, Arthur Bedrosian, wrote to the FDA, acknowledging receipt by Lannett and Cody of the FDA's March 1, 2010 letter. See Exhibit O. Bedrosian noted that Lannett filed its NDA application on February 26, 2010. See Exhibit O. He expressed concern that the letter and the statements contained therein were likely to be used by Roxane to increase its market share further. He also noted that the March 1, 2010 letter

followed the FDA's issuance of a press release and teleconference promoting the approval of Roxane's product, the republication of the March 30, 2009 warning letters (but not the April 9, 2009 follow-up letter extending the enforcement date), and communications with Lannett's major customers (and their trade association) and with the DEA (in which FDA opposed further quota approval for Cody/Lannett). See Exhibit O. The letter concluded by expressing the hope that FDA would be as cooperative with Lannett's NDA as it had been with Roxane's application, in recognition of Lannett's cooperation and actions to assist in alleviating the previous shortage. See Exhibit O.

79. The FDA again denied Lannett's request for expedited review of its NDA. The FDA also suggested that Lannett withdraw the NDA and file an ANDA instead, which would require Lannett to submit different and additional data, resulting in further delay.

80. On June 10, 2010, counsel for Cody/Lannett wrote FDA, requesting its cooperation and advice regarding the crisis situation Cody/Lannett then faced with the NDA review proceeding, and with the compliance date rapidly approaching. See Exhibit P. The email outlined the facts of the situation and noted that, as a result of the FDA's actions, the DEA was denying Cody/Lannett additional product quota, distributors were refusing to stock the product, and that health-care providers' reimbursement for Cody/Lannett's product was in jeopardy. See Exhibit P. The email requested that the FDA either: (1) level the playing field by providing Lannett with the same expedited review as Roxane received; or (2) exercise its enforcement discretion to permit the Product to remain on the market during the pendency of the review of

Lannett's NDA since Cody/Lannett had cooperatively sought FDA approval of its product, the express purpose of the 2006 guidance. See Exhibit P.

81. On June 22, 2010, the FDA responded to the June 10, 2010 email and explained that Lannett's request for expedited review was denied because (once FDA had expedited and approved Roxane's application) there was no longer a drug shortage for concentrated oral Morphine Sulfate solution, an approved product was currently on the market, and the FDA drug shortage staff confirmed that the approved product could cover the market. See Exhibit Q. Cody/Lannett understand from hospices and palliative care communities that use the Product, however, that these medical communities have grave concerns about the future availability and cost of 20 mg/mL concentrated oral Morphine Sulfate Solution if the Cody/Lannett Product is no longer available.

82. The June 22, 2010 response from the FDA further stated that the numerous Roxane applications received priority review because they were all medically necessary; there was a shortage when Roxane's 20 mg/mL application was filed, so the review division worked to get it approved as early as they could so the shortage could be addressed. See Exhibit Q.

83. The June 22, 2010 response also addressed the grandfather claim. The FDA asserted that Cody/Lannett's position had been thoroughly considered and rejected by the FDA, without elaborating the rationale, and still provided no evidence or administrative record to justify the FDA's own, earlier determination that the Product was a "new drug" for which an NDA was required. See Exhibit Q.

84. The response further stated that Roxane's FDA approved product could meet patient supply needs and reiterated FDA's intention to take action against firms that did not conform to the terms set forth in the March 30, 2009 warning letters and the April 9, 2010 and March 1, 2010 follow-up letters after July 24, 2010. See Exhibit Q.

85. On July 12, 2010, Cody/Lannett's counsel met with FDA's lawyers and a representative from CDER's unapproved drug team. Counsel again requested that FDA exercise enforcement discretion to permit Lannett to remain on the market pending completion of FDA's review of its NDA. FDA's lawyers requested information regarding certain studies and outstanding requests for additional information.

86. On July 13, 2010, Cody/Lannett's counsel promptly provided FDA's lawyers with the requested information concerning the status of the studies mentioned during the previous day's meetings and the deadline by which FDA would receive the data from the studies.

87. Cody/Lannett have responded promptly to all of FDA's requests for additional information.

88. Cody/Lannett continue to make the Product under the regulatory apparatus applicable to "drugs," as verified by continuous and detailed post-market surveillance and inspections of both facilities.

89. Cody/Lannett have a history of compliance with the requirement to obtain FDA approval to market new drugs, and Lannett has a number of approved ANDAs.

90. The FDA has permitted the production and sale of the Product for over 15 additional months, despite its statements regarding future enforcement in the March 30, 2009

warning letters and April 9, 2009 follow-up letters, because it is aware of no specific health hazard to the public of continued use of the Product.

91. The FDA's March 30, 2009 warning letters and the April 9, 2009, March 1, 2010, and June 22, 2010 follow-up letters set forth the FDA's definitive position that sale and manufacture of the Product violates the FDCA because the Product is a "new drug" not entitled to grandfathering under the FDCA.

92. The March 30, 2009 warning letters, the April 9, 2009 and June 22, 2010 follow-up letters, and the FDA's actions after the issuance of those letters all constitute affirmative adverse actions against Cody, the manufacturer, and Lannett, the marketer, of the Product. Such actions constitute enforcement which is reviewable by the Court.

93. The FDA created no administrative record prior to concluding the Product was a "new drug" requiring an NDA under the FDCA.

94. The FDA threatened enforcement action against Cody/Lannett with no prior reviewable determination as to whether the Product was a "new drug" for purposes of the FDCA.

95. Subsequent to declaring the Product a "new drug" without creating a record or producing any evidence in support of that determination, the FDA received voluminous evidence from Cody/Lannett establishing that the product is not a "new drug" as that term is defined in the FDCA.

96. The FDA, acting arbitrarily, capriciously, contrary to law, and in abuse of its discretion, ignored all of the evidence submitted, produced no record of contrary evidence, and

relied instead on its initial, wholly unsupported, conclusory assertion that the Product was a "new drug" that required submission of an NDA.

97. The FDA treated Roxane and Cody/Lannett, both of which manufactured and sold 20mg/mL oral Morphine Sulfate solution without FDA approval, differently in the NDA process. The FDA encouraged Roxane to remain in the market and manufacture and sell the product, and worked with Roxane in an expedited manner to approve Roxane's application. At the same time, the FDA acted to prohibit Cody/Lannett from manufacturing and selling the same drugs. The FDA's inconsistent actions were arbitrary, capricious, contrary to law, and an abuse of discretion.

98. Cody/Lannett's NDA, to this date, remains pending while Roxane's has been approved.

99. Cody/Lannett is faced with imminent removal of the Product from the market on July 24, 2010 due to the FDA's denial of expedited processing of Cody/Lannett's NDA, as compared to the FDA's favorable treatment of Roxane.

100. Due to the March 30, 2009 warning letters and the follow-up letters, the DEA has refused to grant Cody/Lannett additional quota of the raw materials necessary to manufacture the Product. As a result, Cody/Lannett will be unable to make the Product and jobs will be lost at Cody's plant in Cody, Wyoming.

101. Cody/Lannett anticipates that if the FDA fails to decide Cody/Lannett's NDA before the July 24, 2010 date and requires Cody/Lannett to stop the manufacturing, marketing, and selling the Product, Cody will be forced to immediately terminate 60% of its 90-person

workforce to protect the viability of its remaining business. The lost jobs will be from every department of Cody. The lost jobs will range from laborers working for $10-12 per hour up to chemists earning more than $60,000. These layoffs will equal at minimum a $2,700,000.00 reduction in Cody's annual payroll.

102. Cody/Lannett anticipates that layoffs will result in the permanent loss of skilled labor from the Cody, Wyoming area. Significantly, Cody is the only pharmaceutical manufacturer in Wyoming and no alternative jobs exist for Cody's skilled employees. Cody/Lannett spends approximately $15,000 to recruit and relocate each skilled employee to Cody, Wyoming. Following layoffs, recruiting and hiring new chemists will be both difficult and expensive if the FDA later approves Lannett's NDA.

103. While the Product currently has 44% market share for this formulation of Morphine Sulfate, indeed the largest market share of concentrated Morphine Sulfate solution in the United States, Cody/Lannett is losing significant market share each day due to the uncertainty and the negative media attention created intentionally by the FDA regarding Cody/Lannett's NDA, both of which have caused many customers to seek alternative suppliers.

104. The Morphine Sulfate solution market is such that any shutdown by the FDA of a manufacturer will result in an overnight loss of virtually the entire market share. Regaining market share could take in excess of three years, if it is even possible.

105. If this Court does not grant Cody/Lannett's requested relief, Cody/Lannett anticipates that it will be forced to permanently cease manufacturing, marketing, and selling the Product.

106. Roxane's artificial monopoly poses a risk of harm to the public insofar as a single source for this medically necessary drug creates a significant possibility of inadequate supply of the drug to hospitals, hospices, and palliative care communities due to possible interruption in the supply chain.

107. Roxane's artificial monopoly poses a risk of harm to the public insofar as allowing a single source to serve the entire market creates a substantial risk of significantly increased prices for 20 mg/mL Morphine Sulfate concentrated oral solution.

108. The public will suffer no harm if Court allows the Product to remain on the market until a final resolution of this case or until the FDA acts on Lannett's NDA, whichever may occur first.

109. The FDA will suffer no harm if this Court allows the Product to remain on the market until a final resolution of this case or until the FDA acts on Lannett's NDA, whichever may occur first.

COUNT I - VIOLATION OF THE APA

(THE FDA FAILED TO DEVELOP AN ADEQUATE RECORD TO SUPPORT ITS DETERMINATION THAT THE PRODUCT WAS A "NEW DRUG" FOR PURPOSES OF THE FDCA IN VIOLATION OF THE APA).

110. The foregoing paragraphs are incorporated by reference as though specifically re-alleged herein.

111. A determination by the FDA that a drug is a "new drug" for purposes of the FDCA is reviewable by this Court under the APA. Weinberger v. Hynson, Wescott & Dunning, Inc., 412 U.S. 609, 627 (1973).

112. Under the APA, this Court must set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); Greater Yellowstone Coal. v. Flowers, 359 F.3d 1257, 1274 (10th Cir. 2004).

113. In conducting this review, the Court must review the agency's "decisionmaking process and determine whether the [agency] examined all relevant data and articulated a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." Olenhouse v. Commodity Credit Corp., 42 F.3d 1560, 1580 (10th Cir. 1994).

114. In addition, in conducting this review, the Court must also determine "whether the agency's action was supported by substantial evidence." Id. at 1576.

115. In making a determination that a drug is a "new drug" for purposes of the FDCA, the "FDA does not have unbridled discretion to do what it pleases. Its procedures must satisfy the rudiments of fair play." Weinberger, 412 U.S. at 627.

116. The requirements of the APA and the rudiments of fair play require, at a minimum, that the FDA develop a sufficient record to support a determination that a drug is a "new drug" for purposes of the FDCA. For, as the Tenth Circuit has noted, a drug is not a "new drug" for purposes of the FDCA simply because the FDA says it is. Rutherford v. United States, 542 F.2d 1137 (10th Cir. 1976).

117. The FDA failed to develop an adequate record to support its determination that the Product is a "new drug" that does not fall within the grandfathering provisions of the FDCA.

118. By failing to develop an adequate record for its determination that the Product is a "new drug" for purposes of the FDCA, the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion in violation of the APA in reaching such a determination.

119. Cody/Lannett have suffered harm and will suffer irreparable harm, including loss of market share, loss of skilled employees, loss of manufacturing capabilities, and loss of business relationships, as a result of the FDA's failure to develop an adequate record prior to making determination that the Product is a "new drug" not entitled to grandfathering treatment under the APA.

120. The harm that Cody/Lannett have suffered and will suffer cannot be quantified monetarily, and monetary compensation for such harm will not be available against the Defendants in any event. See, e.g., Kansas Health Care Ass'n, Inc. v. Kansas Dept. of Social and Rehab. Servs., 31 F.3d 1536, 1543 (10th Cir. 1994).

COUNT II - VIOLATION OF THE APA

(THE FDA IMPROPERLY DETERMINED THAT THE PRODUCT IS A "NEW DRUG" FOR PURPOSES OF THE FDCA IN VIOLATION OF THE APA).

121. The foregoing paragraphs are incorporated by reference as though specifically re-alleged herein.

122. Federal agencies have authority to make determinations only insofar as those determinations are based on a permissible and reasonable construction of the governing statute. See Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842-43 (1984).

123. When an agency determination is "manifestly contrary to the statute," the agency regulation or decision will be found to be arbitrary, capricious, an abuse of discretion, and contrary to law in violation of the APA. See Chevron, 467 U.S. at 844; 5 U.S.C. § 706(2)(A).

124. The grandfathering provision of the FDCA clearly states that a drug is not a "new drug" and is therefore entitled to grandfathering under the FDCA if: (1) the drug was subject to the Food and Drugs Act of 1906 and (2) the drug's labeling at the time contained the same representations concerning the conditions of its use as the drug does now.

125. The Product is not a "new drug" under the FDCA because Morphine Sulfate was subject to the Food and Drugs Act of 1906 and its labeling contained the same representations concerning the conditions of its use as the drug does now. See Exhibit R (see attached as Exhibit K to Plaintiffs' Memorandum of Law in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction).

126. The FDA's determinations that oral Morphine Sulfate solution generally, and the Product specifically, were a "new drug" for purposes of the FDCA were arbitrary, capricious, an abuse of discretion, and manifestly contrary to the plain language of the FDCA and were thus in violation of the APA.

127. Cody/Lannett have suffered harm and will suffer irreparable harm, including loss of market share, loss of skilled employees, loss of manufacturing capabilities, and loss of business relationships, as a result of the FDA's arbitrary, capricious, abuse of discretion, and contrary to law determination that the Product is a "new drug" not entitled to grandfathering treatment under the APA.

128. The harm that Cody/Lannett have suffered and will suffer cannot be quantified monetarily, and monetary compensation for such harm will not be available against the Defendants in any event. See, e.g., Kansas Health Care Ass'n, Inc., 31 F.3d at 1543 (10th Cir. 1994).

COUNT III - VIOLATION OF THE APA

(THE FDA TREATED SIMILARLY SITUATED COMPETITORS, CODY/LANNETT AND ROXANE, DIFFERENTLY IN VIOLATION OF THE APA).

129. The foregoing paragraphs are incorporated by reference as though specifically re-alleged herein.

130. "Government is at its most arbitrary when it treats similarly situated parties differently." Bracco Diagnostics, Inc. v. Shalala, 963 F.Supp. 20, 27-28 (D.D.C. 1997). Thus, while the FDA has discretion in initiating enforcement actions, "once FDA has initiated an enforcement action against certain manufacturers [of an 'unapproved drug'], unless unusual circumstances are present, it must proceed in an equal manner against all such entities." Allergan Inc. v. Shalala, 1994 U.S. Dist. LEXIS 21716 (D.D.C. Nov. 10, 1994). Moreover, "disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious," id., and "[d]eference to administrative discretion or expertise is not a license to a regulatory agency to treat like cases differently." United States v. Diapulse Corp. of Am., 748 F.2d 56, 62 (2d Cir. 1984) (citations omitted).

131. Cody/Lannett and Roxane were similarly situated parties for purposes of submitting NDAs in order to obtain authorization for the manufacture and sale of Morphine Sulfate oral solutions of the 20 mg/mL concentration.

132. The FDA gave Roxane preferential treatment throughout the NDA process, including, but not limited to, providing Roxane with greater assistance in moving through the NDA process and granting Roxane's request for expedited treatment of its supplemental NDA.

133. The FDA gave Cody/Lannett disparate treatment throughout the NDA process, including, but not limited to, substantial delays in scheduling meetings with Cody/Lannett and denying Cody/Lannett's request for expedited treatment of its NDA.

134. In treating Cody/Lannett and Roxane differently throughout the NDA process, the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion in violation of the APA.

135. As a result of this disparate treatment, Roxane is currently the only FDA approved source for 20 mg/mL Morphine Sulfate oral solution. Therefore, Roxane is poised to gain an artificial monopoly, including all of Cody/Lannett's current market share, when the FDA requires Cody/Lannett to remove the Product from the market on July 24, 2010.

136. Cody/Lannett have suffered harm and will suffer irreparable harm, including loss of market share, loss of skilled employees, loss of manufacturing capabilities, and loss of business relationships, as a result of the FDA's arbitrary, capricious, abuse of discretion, and contrary to law actions in granting Roxane preferential treatment over Cody/Lannett throughout the NDA process.

137. The harm that Cody/Lannett have suffered and will suffer cannot be quantified monetarily, and monetary compensation for such harm will not be available against the Defendants in any event. See, e.g., Kansas Health Care Ass'n, Inc., 31 F.3d at 1543.

PRAYER FOR RELIEF

WHEREFORE, Cody/Lannett respectfully request that this Court:

(1) Issue a temporary restraining order and preliminary injunction enjoining the FDA from any enforcement action or attempt to prevent Cody/Lannett from manufacturing, marketing, or selling the Product if such enforcement is based on the FDA's contention that the Product is an unapproved "new drug" for purposes of the FDCA.

(2) Issue a temporary restraining order and preliminary injunction enjoining the FDA from threatening or taking any enforcement action against Cody/Lannett's customers[1] if such threat of enforcement or actual enforcement is based on the FDA's contention that the Product is an unapproved "new drug" for purposes of the FDCA;

(3) Issue a temporary restraining order and preliminary injunction enjoining the FDA from any enforcement action or attempt to prevent Cody/Lannett from manufacturing, marketing, or selling the Product if such enforcement is based on the absence of an approved NDA or ANDA for the Product.

(4) Issue a temporary restraining order and preliminary injunction enjoining the FDA from threatening or taking any enforcement action against Cody/Lannett's customers if such

[1] "Customers" as used in this Prayer for Relief includes all direct customers of Cody/Lannett including wholesalers, distributors, and pharmacies, as well as all legal downstream purchasers and patients using the product.

threat of enforcement or actual enforcement is based on the absence of an approved NDA or ANDA for the Product. See Exhibit S.

(5) Issue a declaratory judgment that the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion in failing to develop an administrative record for its determination that the Product is a "new drug" for purposes of the FDCA and is therefore not entitled to grandfathering under the FDCA.

(6) Issue a declaratory judgment that the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion in determining that the Product is a "new drug" for purposes of the FDCA and is therefore not entitled to grandfathering under the FDCA.

(7) Issue a declaratory judgment that the Product is a not "new drug" for purposes of the FDCA and is therefore entitled to grandfathering under the FDCA such that Cody/Lannett do not need an approved NDA to continue to manufacture, market, and sell the Product.

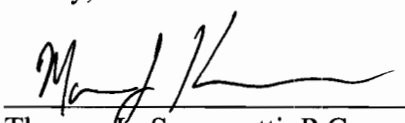
(8) Issue a declaratory judgment that the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion in treating Cody/Lannett and Roxane differently in the NDA process.

(9) Issue a declaratory judgment that the FDA acted arbitrarily, capriciously, contrary to law, and abused its discretion in denying Cody/Lannett's request for expedited treatment of Lannett's NDA after having previously granted Roxane expedited treatment for its supplemental NDA.

(10) Enter an order awarding Cody its reasonable attorney's fees and costs of prosecuting this action; and

(11) Grant such other relief as this Honorable Court deems necessary and appropriate.

Respectfully submitted this 21st day of July, 2010.



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